

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

**IN RE: ETHICON, INC., PELVIC REPAIR
SYSTEM PRODUCTS LIABILITY
LITIGATION**

**Master File No. 2:12-MD-02327
MDL 2327**

**JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE**

THIS DOCUMENT RELATES TO:

**ALL PLAINTIFFS LISTED IN
PLAINTIFFS' MOTION**

**MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO
EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF TED ROTH, M.D.**

Dr. Roth is a board-certified urogynecologist who has performed approximately 1,200 surgical implantations of midurethral slings, including hundreds of procedures using the TVT, TVT-O, and Prolift+M. He estimates that he performs 20 sling excision or revision procedures a year, and has performed approximately 60 mesh excisions or revisions related to the treatment of pelvic organ prolapse (POP). Despite Dr. Roth's extensive qualifications, Plaintiffs seek to exclude his opinions about product warnings and instructions for use (IFU), the design of the mesh products, and their safety and efficacy.¹

As more fully explained below, Defendants Ethicon, Inc., Ethicon, LLC, and Johnson & Johnson (Ethicon) ask the Court to deny Plaintiffs' motion. Dr. Roth is well qualified to offer his proposed testimony regarding the safety and efficacy of these products and related matters, which is well supported and based on a reliable methodology. He relied not only on his extensive

¹ As Plaintiffs note, Dr. Roth's Prolift+M report also covers the Prolift and Gynemesh PS devices, but Ethicon has not designated Dr. Roth as an expert on these devices for the cases to which Plaintiffs' motion applies. Pls.' Mem. (Dkt. 3668) at 3 n.1; Ex. A to Pls.' Mot. (Dkt. 3668-1), List of Cases.

experience, but also a thorough review and analysis of the peer-reviewed medical literature and related materials. His opinions are based on “good grounds” and will assist the trier of fact in understanding the evidence and determining facts at issue—namely, whether these products are defective and whether Plaintiffs can meet their burden of establishing general and specific causation.

ARGUMENTS AND AUTHORITIES

I. Dr. Roth is qualified to testify about risks that are within the common knowledge of physicians.

Dr. Roth proposes to testify regarding the risks of mesh procedures, whether those risks are commonly known to pelvic surgeons, and whether risks for which there is scientific support are included in the IFUs. See Ex. B to Pls.’ Mot. (Dkt. 3668-2), Roth TVT Report at 17-22, 27-28; Ex. C to Pls.’ Mot. (Dkt. 3668-3), Roth Prolift Report at 12-20, 26-27, 31-32. Dr. Roth is qualified to offer these opinions based on his experience and his review and analysis of the relevant medical literature. As this Court has acknowledged, “doctors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings.” *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *15 (S.D.W. Va. Apr. 24, 2015) (quoting *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09-md-02100, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011)).

Dr. Roth’s opinions that these risks are common knowledge among pelvic floor surgeons are supported by his own training and extensive clinical experience, as well as his training of other surgeons. See Ex. B to Pls.’ Mot. (Dkt. 3668-2), Roth TVT Report at 2; Ex. C to Pls.’ Mot. (Dkt. 3668-3), Roth Prolift Report at 2. This information will be helpful to the jury because a manufacturer is not liable for a failure to warn of risks of which the physician was already

independently aware. *See, e.g., Talley v. Danek Med., Inc.*, 7 F. Supp. 2d 725, 730 (E.D. Va. 1998) (citing *Stanback v. Parke, Davis & Co.*, 657 F.2d 642, 645 (4th Cir. 1981)), *aff'd*, 179 F.3d 154 (4th Cir. 1999).

Indeed, Ethicon, like other medical device manufacturers, has no duty to warn pelvic-floor surgeons of risks commonly known to attend pelvic-floor surgery. *See Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (instructing that the duty to warn is of dangers “not well known to the medical community”); *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2015 WL 4944339, at *7 (S.D.W. Va. Aug. 19, 2015) (“The medical device manufacturer, however, need not warn about ‘risks already known to the medical community.’”). As stated generally in the Restatement (Third) of Torts: Products Liability § 2 cmt. j, a product seller “is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users.” *See also* RESTATEMENT (SECOND) OF TORTS §§ 388(b), 402A cmt. j. In fact, the FDA has said that information may be omitted from labeling “if, but only if, the article is a device for which directions, hazards, warnings, and other information are *commonly known* to practitioners licensed by law to use the device.” 21 C.F.R. § 801.109(c) (emphasis added). Moreover, the device IFUs restrict their use to surgeons familiar with traditional surgical techniques used to treat stress urinary incontinence. *E.g.*, Ex. 1, TVT-O IFU, HMESH_ETH_11043472 (stating device should be used “only by physicians trained in the surgical treatment of stress urinary incontinence and specifically in implanting the GYNECARE TVT Obturator device”).

Plaintiffs nonetheless argue that Dr. Roth should be precluded from offering opinions regarding the adequacy of the warnings accompanying Ethicon’s mesh products because he is unfamiliar with the FDA regulations governing IFUs. Pls.’ Mem. (Dkt. 3668) at 4–7. The Court

should reject Plaintiffs' argument because Dr. Roth does not propose to testify about regulatory matters. Instead, Dr. Roth proposes to testify on the following topics regarding risks and warnings: the risks inherent in all surgeries to treat SUI; his opinion that all of those risks are commonly known to experienced pelvic surgeons; the rates of mesh exposure and infection supported by the scientific literature; his analysis of the studies of mesh shrinkage, pelvic pain and dyspareunia; his opinions regarding the clinical import of inflammation associated with polypropylene mesh devices; post-implantation changes and biomechanics; and the lack of support in the scientific literature for purported defects and complications including degradation and particle loss, toxicity, bacterial slime/bio-film, and carcinogenesis. Ex. B to Pls.' Mot. (Dkt. 3668-2), Roth TVT Report at 17–26.

With respect to the Prolift+M, he proposes to testify about: the risks inherent in all surgeries to treat POP, and his opinion that all of these risks are commonly known to experienced pelvic surgeons; the scientific literature regarding rates of exposure not only of mesh but also of permanent sutures; the impact of a surgeon's experience and surgical volume on surgical outcomes; the risk factors for mesh-based complications, including mesh exposure, infection, mesh shrinkage, and dyspareunia; the biocompatibility of polypropylene mesh; post-implantation changes and biomechanics; and the lack of support in the scientific literature for purported defects and complications including toxicity, bacterial slime/bio-film, degradation, and carcinogenesis. Ex. C to Pls.' Mot. (Dkt. 3668-3), Roth Prolift Report at 12–25.

These opinions are grounded in the scientific method, the law, within Dr. Roth's expertise, and consistent with the Court's Wave 1 rulings. Indeed, this Court has "expressed no opinion" about "whether certain risks were common knowledge," and therefore has not

precluded this expert testimony. *See, e.g., In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582231, at *3 n.2 (S.D.W. Va. Sept. 1, 2016).

And Dr. Roth is well qualified to offer these opinions. He is a board-certified urogynecologist who has performed approximately 1,200 surgical implantations of midurethral slings. Ex. B to Pls.’ Mot. (Dkt. 3668-2), Roth TVT Report at 2. He currently performs roughly 110 to 120 sling implantations per year, of which around 90% are TVT-O and 10% are retropubic TVT. *Id.* He has also implanted approximately 160 Prolifts and 80 Prolift+Ms, as well as other transvaginal mesh kits, and has performed hundreds of surgeries using Gynemesh PS. Ex. C to Pls.’ Mot. (Dkt. 3668-3), Roth Prolift Report at 2. He estimates that he performs around 20 sling excision or revision procedures a year. Ex. E to Pls.’ Mot. (Dkt. 3668-5), Roth 3/16/17 TVT Dep. Tr. 69:1–4. With respect to excisions related to the treatment of POP, he estimates that he has performed 60 mesh excisions or revisions from sacrocolpopexies and POP kits, of which roughly two-thirds involved Prolift or Prolift+M. Ex. D to Pls.’ Mot. (Dkt. 3668-4), Roth 3/17/17 Prolift+M Dep. Tr. 46:17–47:22.

Ethicon is mindful of the Court’s Wave 1 ruling that experts without additional regulatory expertise on product labeling and compliance cannot testify “about what an IFU should or should not include.” *See, e.g., In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4557036, at *3 (S.D.W. Va. Aug. 31, 2016). Dr. Roth will not be offering opinions about what should or should not be included in an IFU. Ethicon respectfully submits, however, that risks that are within the common knowledge of physicians are risks that would not, as a matter of logic, be included in an IFU. This logical result, however, does not mean that an expert’s common-knowledge testimony should be excluded under the Court’s exclusionary “additional expertise” directive. Instead, the Court’s directive goes to the lack of

expertise in regulatory requirements and compliance, not whether a particular risk is within the common knowledge of physicians. *See Wise v. C.R. Bard, Inc.*, No. 2:12-cv-01378, 2015 WL 521202, at *14 (S.D.W. Va. Feb. 7, 2015) (distinguishing between an expert’s expertise “in the requirements for product labeling” and the expert’s qualifications as a practicing physician to testify about risks provided in the text of the product’s labeling).

In accordance with this distinction and the Court’s limitations, Dr. Roth will not testify about the regulatory requirements for product labeling for the IFUs at issue here or what the IFUs should or should not include. But he is qualified by education, training, and experience to give opinions about what risks are within the common knowledge of surgeons who perform pelvic-floor surgery. *E.g.*, Ex. B to Pls.’ Mot. (Dkt. 3668-2), Roth TVT Report at 2–3. Any disagreement Plaintiffs may have with Dr. Roth’s opinions on this issue goes to weight, not admissibility.

II. Dr. Roth’s warnings opinions are reliable.

Dr. Roth relied not only on his own surgical experience, but he also relied on his research and teaching, a thorough review and analysis of the medical literature, his analysis of the IFUs and professional education materials for surgeons using the products at issue, his participation in professional medical societies, discussions with his peers, and his review of deposition testimony and exhibits. *E.g.*, Ex. B to Pls.’ Mot. (Dkt. 3668-2), Roth TVT Report at 2–3. He estimates that he spent at least 50 hours reviewing the medical literature in preparing his report. Ex. E to Pls.’ Mot. (Dkt. 3668-5), Roth 3/16/17 TVT Dep. Tr. 41:12–16. And he supports each of his opinions with numerous scientific articles and studies, which he discusses in detail in his report. Ex. B to Pls.’ Mot. (Dkt. 3668-2), Roth TVT Report at 17–26; Ex. C to Pls.’ Mot. (Dkt. 3668-3), Roth Prolift Report at 12–25.

Dr. Roth does not purport to give his warnings opinions based merely on risks that he observed in his own practice. The Court's previous rulings precluding this testimony therefore do not apply. *See, e.g., Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 584 (S.D.W. Va. 2014), *as amended* (Oct. 29, 2014); *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, 2014 WL 12685965, at *16 (S.D.W. Va. Nov. 20, 2014). Instead, Dr. Roth relies on a large pool of scientific literature and studies, combined with the clinical experience and evaluation of many physicians and medical organizations, to support his conclusion that certain risks do not occur or are risks commonly known to pelvic-floor surgeons. If Plaintiffs disagree with Dr. Roth's conclusions, that disagreement goes to the weight the jury should give to his testimony, not its admissibility, and can be addressed on cross-examination. *Tyree*, 54 F. Supp. 3d at 538.

Plaintiffs nonetheless argue that the Court should preclude Dr. Roth from offering opinions regarding whether certain risks of implanting mesh are commonly known because those opinions are unreliable. Pls.' Mem. (Dkt. 3668) at 7–8. They claim they are so because he cannot state a precise percentage of pelvic-floor surgeons in the United States who knew or did not know of the particular alleged risks of “excessive contraction or shrinkage of the mesh, vaginal scarring, tightening, or shortening.” *Id.* Yet this level of statistical precision is not required. Dr. Roth supports his opinions regarding what surgical risks are commonly known among his peers with his own training, his experience teaching other surgeons, his familiarity with the literature produced and reviewed by surgeons in this community, and his routine interactions with his colleagues at conferences and other periodic gatherings. These bases provide sufficient support for his opinions regarding the commonly known risks of mesh surgeries.

III. Dr. Roth—an experienced pelvic-floor surgeon—is qualified to opine about mesh properties; he is not opining about the process of designing a product.

Plaintiffs ask the court to preclude Dr. Roth from “opining about the design of the subject products, including offering opinions on the most suitable mesh for the treatment of SUI or POP.” Pls.’ Mem. (Dkt. 3668) at 8. The Court should reject Plaintiffs’ request because Dr. Roth is not offering an opinion about the process of designing a product. But he is qualified to testify about whether polypropylene and other meshes are suitable for the treatment of SUI and POP, his opinions on those topics are reliable, and Plaintiffs have failed to identify any other challenged opinions with sufficient specificity.

A. Dr. Roth’s mesh-properties opinions

Dr. Roth offers opinions regarding the appropriateness of the use of Prolene mesh in the products at issue in terms of biocompatibility and alleged risks. *See supra* Section I (listing the alleged risks and mesh characteristics discussed in his reports). These opinions include his conclusions that there is a lack of scientific evidence to support Plaintiffs’ theories that the mesh used in the products at issue degrades, is toxic, promotes the development of bacterial slime or bio-film, or is carcinogenic. *Id.* He also offers opinions regarding the appropriateness and/or availability of other meshes, including Vypro, Ultrapro, and PVDF/Dynamesh. Ex. B to Pls.’ Mot. (Dkt. 3668-2), Roth TVT Report at 27; Ex. C to Pls.’ Mot. (Dkt. 3668-3), Roth Prolift Report at 25–26. He supports each of these opinions with a detailed discussion of the relevant scientific literature and the conclusions he reached based on his analysis. *See* Ex. B to Pls.’ Mot. (Dkt. 3668-2), Roth TVT Report at 17–27; Ex. C to Pls.’ Mot. (Dkt. 3668-3), Roth Prolift Report at 12–26.

B. Dr. Roth's mesh-properties opinions are consistent with this Court's Wave 1 rulings.

This Court has repeatedly instructed that an expert with Dr. Roth's experience and background is well-qualified to offer opinions about various mesh properties, including opinions about the most suitable mesh for the treatment of SUI or POP. *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493585, at *3 (S.D.W. Va. Aug. 25, 2016) (finding board-certified urologist Dr. Anhalt's "extensive clinical experience, combined with a review of peer-reviewed literature, qualifies [him] to opine on mesh's reaction to and effect on the human body, and relatedly, the safety and efficacy of mesh products"); *see also In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4944702, at *3 (S.D.W. Va. Aug. 30, 2016) (rejecting Plaintiffs' argument that board-certified urologist Brian Schwartz, M.D., is unqualified to offer opinions about material properties of mesh because he is not trained as a polymer scientist, medical device engineer, or pathologist and has not analyzed explanted mesh under a microscope); *accord In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493535, at *3 (S.D.W. Va. Aug. 25, 2016) (rejecting plaintiffs' argument that Dr. Bales is unqualified to offer opinions about whether mesh degrades because he is not an engineer); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582210, at *4 (S.D.W. Va. Sept. 1, 2016) (rejecting plaintiffs' argument that Dr. Horbach is not qualified to offer opinions about mesh properties because she never designed a mesh product); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536875, at *3 (S.D.W. Va. Aug. 30, 2016) (rejecting plaintiffs' argument that Dr. Serels is not qualified to offer various mesh properties opinions because he is not an engineer or pathologist); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493364, at *2-3 (S.D.W. Va. Aug. 25, 2016) (rejecting plaintiffs' argument that Dr. Toglia

is not qualified to offer opinions about polypropylene safety and mesh weight because he is not an engineer).

C. Dr. Roth is not offering opinions about the process of designing a product.

Plaintiffs have not specifically identified any purported “design” opinions they seek to exclude. *See* Pls.’ Mem. (Dkt. 3668) at 8–11. Instead, they urge the Court to preclude Dr. Roth from giving what they characterize as “design opinions” generally. *Id.* The Court should reject Plaintiffs’ argument because “they do not explain or identify these opinions with sufficient specificity.” *In re: Ethicon, Inc.*, 2016 WL 4493585, at *3. As they have done in the past, Plaintiffs broadly “argue that the expert at issue lacks the particularized skill, knowledge, experience, education, or training that is necessary to provide opinions about the process of designing a product,” including, for example, “opinions about pre-marketing product testing and product development.” *Id.*; *see also* Pls.’ Mem. (Dkt. 3668) at 8–11 (regarding Dr. Roth’s lack of experience designing mesh products or familiarity with Defendants’ internal design documents).

As this Court recognized repeatedly in its Wave 1 rulings, an expert’s “mere utterance” of the word “design” does not transform the expert’s opinion into a design opinion. *In re: Ethicon, Inc.*, 2016 WL 4493585, at *3. It is only when the expert offers opinions “about the process of designing a product” that the expert can be considered to have offered a design opinion. *Id.* (rejecting plaintiffs’ argument to exclude Dr. Anhalt’s “design” opinion because he did not offer any opinions about the process of designing a product); *see also, e.g., In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4547053, at *3 (S.D.W. Va. Aug. 31, 2016) (same as to Dr. Grier); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4542054, at *3 (S.D.W. Va. Aug. 30, 2016) (same as to Dr. Elser); *In*

re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig., MDL No. 2327, 2016 WL 4958312, at *3-4 (S.D.W. Va. Aug. 25, 2016) (same as to Dr. Carbone), among others.

Like Drs. Anhalt, Grier, and Elser in these cases, Dr. Roth offers no opinions about the process of designing a product. Plaintiffs' criticisms about his lack of product design experience should be rejected.

IV. Dr. Roth is qualified to offer opinions on the safety and efficacy of the TVT, TVT-O, and Prolift+M, and these opinions are reliable.

A. He is qualified to offer these opinions.

As discussed, Dr. Roth has extensive clinical, surgical, research, and teaching experience. *See supra* Section I. He has also conducted a thorough review and analysis of the peer-reviewed scientific literature, which he discusses extensively in his reports. *Id.* This Court has repeatedly found that such experience, in combination with a thorough analytical review of the scientific literature, provides ample qualification to offer opinions on the safety and efficacy of mesh devices such as those at issue here. *See, e.g., In re: Ethicon, Inc.*, 2016 WL 4493585, at *3; *In re: Ethicon, Inc.*, 2016 WL 4944702, at *3; *see also Tyree*, 54 F. Supp. 3d at 585 (permitting board-certified urologist with no stated "design" expertise to testify to the safety and effectiveness of mesh based on his extensive clinical experience and citation to "numerous studies and academic papers throughout his expert report to support his opinion that the Obtryx is both safe and effective"); *Wilkerson v. Boston Scientific Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at *24 (S.D.W. Va. May 5, 2015) (finding pelvic surgeon was qualified to offer opinions about the safety and efficacy of the Advantage Fit based on his clinical experience implanting 70 to 80 of defendant's sling products, his experience teaching other surgeons how to perform the surgery, his experience with competitors' products, and his review of the existing literature).

Like the experts in these cases, Dr. Roth's experience qualifies him to offer opinions on the safety and efficacy of the TVT, TVT-O, and Prolift+M.

B. His safety and efficacy opinions are reliable.

Dr. Roth's opinions regarding the safety and efficacy of the TVT and TVT-O are supported not only by his clinical experience but also by the numerous scientific studies, scientific articles, and statements of professional societies he relied on. Ex. B to Pls.' Mot. (Dkt. 3668-2), Roth TVT Report at 3–26. These include studies of traditional and non-surgical treatments for stress urinary incontinence (SUI), clinical trials of the TVT and TVT-O, systematic reviews of studies involving these and other midurethral slings, professional society statements, and FDA communications. *Id.* Dr. Roth notes that the medical community has conducted over 100 randomized controlled trials of the TVT and over 60 of the TVT-O, and that “[b]oth have been analyzed in numerous systematic reviews and meta-analyses, which provide the highest level of medical and scientific evidence” *Id.* at 8–9.

The combination of Dr. Roth's experience and his review of the scientific literature provide good grounds for his opinions. *See, e.g., Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 714 (S.D.W. Va. 2014) (A physician's “knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under *Daubert*.”); *Tyree*, 54 F. Supp. 3d at 585 (finding that board-certified urologist's opinions regarding mesh safety and efficacy were reliable where they were based on his observation of “minimal complications in his clinical practice,” which were “on par with the findings” in the studies he cited throughout his expert report).

Plaintiffs nonetheless challenge the reliability of Dr. Roth's opinions on safety and efficacy on five limited grounds. First, they argue that he does not “provide information

regarding the differences in safety and efficacy between the TVT and TVT-O.” Pls.’ Mem. (Dkt. 3668) at 11. This is incorrect. *See* Ex. B to Pls.’ Mot. (Dkt. 3668-2), Roth TVT Report at 15 (discussing Laurikainen 2014 randomized control trial comparing the TVT and TVT-O).

Second, Plaintiffs object to Dr. Roth’s reliance on meta-analyses that combine studies of the TVT and TVT-O with studies of other midurethral slings. Pls.’ Mem. (Dkt. 3668) at 11–12. But as Dr. Roth explained, the results of these systematic review and meta-analyses, which offer the highest level of scientific and medical evidence, are consistent with the results of the controlled trials for TVT and TVT-O and with his experience doing approximately 1,200 procedures. Ex. E to Pls.’ Mot. (Dkt. 3668-5), Roth 3/16/17 TVT Dep. Tr. 170:5–171:1. And while Plaintiffs specifically cite the Novara, Rheman, Barber, and Schimpf studies (Pls.’ Mem. (Dkt. 3668) at 11), they ignore the Tommaselli systematic review and meta-analysis of 49 studies, “the vast majority of which used TVT and TVT-O” midurethral slings. Ex. B to Pls.’ Mot. (Dkt. 3668-2), Roth TVT Report at 9.

Third, Plaintiffs assert that Dr. Roth “cherry-picks data.” Pls.’ Mem. (Dkt. 3668) at 12. This argument fails because Plaintiffs do not identify any studies they allege Dr. Roth failed to consider.

Fourth, Plaintiffs ask the Court to exclude testimony regarding Dr. Roth’s “opinion that his own patients who have been implanted with the Prolift+M device have between an 8 and 15 percent exposure rate.” Pls.’ Mem. (Dkt. 3668) at 13. Yet this opinion, which does not appear in Dr. Roth’s report, was elicited by Plaintiffs. Ex. D to Pls.’ Mot. (Dkt. 3668-4), Roth 3/17/17 Prolift+M Dep. Tr. 47:23–50:10. To the extent that Dr. Roth intends to offer opinions regarding exposure rates, they are those expressed in his report, which are based on the peer-reviewed medical literature. *See* Ex. C to Pls.’ Mot. (Dkt. 3668-3), Roth Prolift Report at 13 (discussing

the rate of mesh exposure found in the 2016 Cochrane review, which was 12 percent, with only eight percent requiring surgical intervention). While Dr. Roth noted in his report that this rate is consistent with the rate that he sees in his own practice (*id.*), that observation does not render his opinions inadmissible. This Court has recognized that a physician may testify that complication rates found in the literature are verified by his personal experience. *See, e.g., Tyree*, 54 F. Supp. 3d at 585 (denying motion to exclude expert’s opinions regarding safety and efficacy where they were based on “the fact that he has observed minimal complications in his clinical practice” and his explanation that his clinical experience was “‘on par with the findings in [the] studies’ he cites throughout his expert report”).

Finally, Plaintiffs urge the Court to preclude Dr. Roth “from testifying about any difference in safety and efficacy rates between the TVT mechanically cut mesh and the TVT laser cut mesh.” Pls.’ Mem. (Dkt. 3668) at 14. Plaintiffs assert that “Dr. Roth has admitted that his opinions in that regard are rooted solely on his flawed, unreliable analysis of his own patients,” and that he testified, “Globally, I can’t make a comment on that.” Pls.’ Mem. (Dkt. 3668) at 14 (citing Ex. E to Pls.’ Mot. (Dkt. 3668-5), Roth 3/16/17 TVT Dep. Tr. 20:22–21:18).

Plaintiffs’ assertion is incorrect. Dr. Roth did testify that he pulled approximately 100 patient charts (divided roughly equally between mechanically cut and laser-cut TVT slings) and, on reviewing them, observed “[r]eally no differences between . . . the two groups.” Ex. E to Pls.’ Mot. (Dkt. 3668-5), Roth 3/16/17 TVT Dep. Tr. 24:23–25:12. This review does not provide the sole basis for his opinions, however. He has extensive clinical experience with both products, and has “seen no difference in efficacy or adverse events” between the two. *Id.* at 19:11–20:21; *see also* Ex. B to Pls.’ Mot. (Dkt. 3668-2), Roth TVT Report at 2 (stating that he performs roughly 110 to 120 sling implantations per year, of which around 90% are TVT-O and 10% are

retropubic TVT). He found nothing in his review of the medical literature to contradict this view. *See* Ex. E to Pls.' Mot. (Dkt. 3668-5), Roth 3/16/17 TVT Dep. Tr. 19:11–20:21 (testifying that he is not aware of any head-to-head studies comparing mechanically and laser-cut mesh “in terms of efficacy or safety profile”). And Plaintiffs have not identified any contrary studies that Dr. Roth failed to consider in forming his opinions. *See* Pls.' Mem. (Dkt. 3668) at 13–14.

At bottom, Dr. Roth's opinions on the safety and efficacy of the TVT and TVT-O are well supported by the combination of his clinical experience and his review of the medical literature, and are therefore reliable.

CONCLUSION

For the reasons stated above, the Ethicon respectfully requests that the Court deny Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Ted Roth, M.D.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on April 27, 2017, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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